

LUD 5543.3 CONT (10027207)REMARKS

Claims 53-56 are added. Please see page 31, lines 1-6, for support.

Points 2 and 3 of the Office Action do not require comment. Please see applicants remarks at page 6 of the prior amendment.

Nor does point 4 require comment. The Examiner has not acted on claims 51 and 52, as presented in the amendment of December 11, 2003.

Applicants do not understand the Examiner's comments at point 6 of the Office Action. What are applicants to comment upon? The Ebert application speaks for itself. Applicants cannot comment on what another applicant says or believes. Hence, the "invitation" cannot be responded to, because it is not understood.

The Examiner has rejected claims 1, 3, 4, 7, 8, 10, 14-16, 18, 19, and 50 under 35 U.S.C. § 112, first paragraph as allegedly being non-enabled. Applicants traverse.

The Examiner argues that applicants have not disclosed any nucleic acid molecules other than those consisting of SEQ ID NOS: 7, 8, 24, and 25, which are TIFs activating STAT3.

This is not true. The case law is absolutely clear that the description of the generic disclosure set forth in the specification and claims is a de facto disclosure of all molecules which fall within the defined, and claimed group of compounds. Applicants are entitled to the presumption that the specification enables the broad claim. It is the Examiner's burden to rebut this presumption, and the Examiner has not done so.

According to the Examiner, "Neither has Applicant disclosed the structural basis or nexus for activation of STAT3 by the T cell inducible factor (TIF) encoded by the disclosed nucleic acids consisting of cDNA and genomic sequences of TIF."

No requirement exists in the law such that an applicant must disclose a "structural basis or nexus" for how a molecule functions, unless that "structural basis or nexus," (whatever this means), is claimed. Applicants claim that molecules as defined by the hybridization conditions will perform the recited function. That is all they need to show. This has been shown. The burden is with the Examiner to show that molecules which fall within the claim scope would not function as claimed, or that undue experimentation would

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be required to identify such molecules. Generalizations which are not linked to the claims are not sufficient.

The Examiner then provides examples of "sufficient biochemical information." One of the items listed is molecular weight. This is recited in the claims. Applicants have pointed this out, and the Examiner continues to ignore it.

The Examiner goes on to state that:

"While applicant relies upon a common function of inducing STAT3 applicant has not addressed the diversity of structure and function of T cell inducible factors disclosed and not disclosed in the specification."

This statement is very misleading as it suggest that inducing STAT3 is the only property recited in the claims. It is not, as this is a recited requirement for hybridization. It is agreed that molecules which activate STAT3 and hybridize to the recited sequence at the recited properties will have some diversity of structure; however, it is contended and has been shown, that molecules satisfying these requirements are disclosed. Again, it falls to the Examiner to show that there are sufficient molecules which, do NOT satisfy the criteria to rebut the presumption of enablement. This has not been shown.

The Examiner then goes on to argue that because certain molecules that are disclosed and fall within the scope of the claims differ in some properties, enablement is lacking.

There is no requirement that members of a claimed genus exhibit identical or even similar properties, across their entire range of properties. Again, the Examiner is reminded that claim language controls, and the issue is whether the Examiner can show that there are molecules which hybridize to the reference molecule do not activate STAT3. Again, applicants point out that this isn't shown.

The Examiner then makes the following cryptic statement:

"T cell inducible factors, including those encoded by SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 24, and SEQ ID NO: 25, which stimulate STAT3, that is, they are not related as a ligand receptor binding pair."

This was cryptic the first time the Examiner stated it, and it remains cryptic. Clearly, there is text missing, which the Examiner has chosen not to supply. With respect to the

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Examiner's sideswiping of the fact that applicants do not understand the issue because it is presented cryptically, there is absolutely no requirement that a claimed molecule, which encodes an activates molecule encode a direct ligand. Again, support for these novel propositions is required, and none is provided.

The Examiner then turns to the non-prior art publications of the inventions, which show that some of the molecules exhibit different properties.

Again, applicants pose the following two questions:

- (i) do these non-prior art references show that the molecules disclosed DO NOT hybridize to SEQ ID NO: 7, 8, 24, or 25, at the recited conditions of stringency?
- (ii) do these non-prior art references show that the claimed molecules do not stimulate STAT3 production?

The record is silent on this, undoubtedly because the references do not show this. Indeed, the Examiner admits, at page 5, that STAT3 was induced, as the references show.

The comments at the top of page 5, i.e., paragraphs 2-5, are noted, but do not make sense. They are viewed as merely comments on the art which again, have no bearing on the invention as claimed.

Skolnick, cited by the Examiner, relates to the searching and identification of molecules via computerized homology searching. Whatever issues are involved in such searching are irrelevant to the claims, since applicants do not require, do not suggest, and do not even mention searching for relevant molecules via computer directed homology searches. Applicants advocate, and claim, doing hybridization studies under clearly recited conditions.

Similarly, with respect to the discussion at page 6 of the Office Action, this is elaborate and irrelevant, as it does not address the issue of claimed subject matter.

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In view of the foregoing, reconsideration and withdrawal of all rejections, and allowance of this application are believed proper and urged.

Respectfully submitted.

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